



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/810,501

03/19/2001

Prem S. Paul

201503US55XD

1105

7590

06/15/2005

Sharon E. Crane, Ph.D.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/810,501	Applicant(s) PAUL ET AL.	
	Examiner Shanon Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
4a) Of the above claim(s) 1-29 and 32-38 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 30,31 and 39-41 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5.0.0

Art Unit: 1648

DETAILED ACTION

In the amendment submitted March 28, 2005, applicant amended claims 30 and 39. Claims 1-41 are pending, claims 1-29, 32-38 are withdrawn from consideration due to non-elected subject matter and claims 30, 31 and 39-41 are under consideration.

Upon reconsideration of the prior art, it is determined that new grounds of rejection are required. The examiner sincerely apologizes for any inconvenience applicant experiences. The examiner would also like to extend thanks to applicant's representative for the time spent discussing the merits of this case.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant states that the claims are not drawn to identifying any particular strain of PRRSV. Rather, the primer sets of claims 30 and 31 are designed to bind to Iowa strain ISU-12 (VR2385) and not to a European strain.

Applicant's arguments have been fully considered, but are found unpersuasive. Since the primers are only required to bind to Iowa strain ISU-12 (VR2385) and not to any European PRRSV strain, it is evident that the kit would not be able to "differentially diagnose" North American and European strains because the strains are amplified, i.e. European, would not be detected by the kit. It is maintained that a diagnosis could not be made in the absence of

Art Unit: 1648

amplification. It is suggested that applicant delete "for the differential diagnosis...(PRRSV)" from claim 30 to obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for primers that bind to common sequences between Iowa strain ISU-12 (VR 2385) and Lelystad to amplify Iowa and Lelystad PRRS viruses, does not reasonably provide enablement for detecting Iowa and PRRS viruses with the specific primer pairs recited in claim 41. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a kit comprising a first primer and a second primer that are 10 to 50 nucleotides in length that hybridize to PRRSV Iowa strain ISU-12 (VR 2385) and the Lelystad virus. Claim 41 recites specific primer pairs consisting of SEQ ID NOs: 8-12 that are used in the kit of claim 39. Applicant's representative informed the examiner that one of the inventors recently clarified that the primers listed in claim 41 were not able to amplify both European and Iowa strains, as the specification appears to teach on page 88, line 24 to page 89, line 5. For this reason, it is determined that claim 41 is not enabled for amplification of the intended targets recited in claim 39. The examiner considered a few of the specific regions selected for hybridization used on page 88-89 regarding primers SEQ ID NOS: 8-12 by close analysis of Figures 8 and 9. It is determined that failure to amplify both Lelystad and the Iowa

Art Unit: 1648

strains resulted from using Lelystad primer sequences that slightly differed from the corresponding region within the Iowa strain. Upon further inspection of Figures 8-11, 17 and 21 in view of applicant's remarks on page 16 of the response, it is agreed that there are a number of regions within both Lelystad and Iowa strains that have more than 10 nucleotide sequences in common that could be selected for primer design to amplify both Lelystad and Iowa strains by one skilled in art.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wensvoort et al. (WO 92/21375).

This reference was previously applied against claims 30 and 31 in the Office action of August 9, 2002. This art is no longer applicable against claims 30 and 31 due to the most recent amendments to the claims. However, upon reconsideration, it is determined that this art is applicable against claims 39 and 40.

Since claims 39 and 40 recite features that are not disclosed in parent applications 08/131,625 or 07/969071, the claims receive the effective filing date of 08/30/1994, i.e. September 1, 1994.

Art Unit: 1648

Claims 39 and 40 are drawn to a diagnostic kit comprising a first and a second primer that are 10-50 nucleotides in length that hybridize to ISU-12 (VR 2385) and Lelystad and a reagent that allows detection of the amplified product.

Wensvoort et al. claim a diagnostic kit comprising nucleic acid probes and primers derived from the genome of the Lelystad virus and fluorescent reagents that allow detection of the amplified product, see claim 21 and page 21, line 15 to page 22, line 21. Although Wensvoort et al. do not teach that the primers that would also bind to ISU-12 (VR 2385), it is determined that since the primers of Wensvoort et al. correspond to any portion of the Lelystad genome, primers that comprise any portion of the Lelystad genome that share the same sequence with ISU-12 (VR 2385) anticipate the claims, even though sequence similarity was unrecognized at the time. “[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it.” See *In re Oelrich*, 666 F.2d at 581. Additionally, the courts have determined that “[I]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.” See *Mehl/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. See *Mehl/Biophile Int’l Corp. v. Milgraum* 192 F.3d 1362, 1365 (Fed. Cir. 1999); *Atlas Power Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Therefore, it is determined that the primers corresponding to any portion of the Lelystad genome are anticipated or rendered obvious by Wensvoort et al.

Art Unit: 1648

Allowable Subject Matter

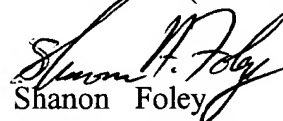
The primers recited in claims 30 and 31 require sequences specific to ISU-12 (VR 2385). The prior art does not teach or suggest ISU-12 (VR 2385) or any sequences that are specific to the strain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
Art Unit 1648